In the Supreme Court of the United States

OCTOBER TERM, 1974

No. 73-1700

NATIONAL NUTRITIONAL FOODS ASSOCIATION AND SOLGAR CO., INC., PETITIONERS

v.

ALEXANDER M. SCHMIDT, COMMISSIONER OF FOOD AND DRUGS, AND CASPAR W. WEINBERGER, SECRETARY OF HEALTH, EDUCATION AND WELFARE

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR THE RESPONDENTS IN OPPOSITION

OPINIONS BELOW

The order of the court of appeals (Pet. App. B) summarily affirming the decision of the district court is not officially reported. The opinion of the district court (Pet. App. A) is reported at 367 F. Supp. 889.

JURISDICTION

The judgment of the court of appeals, affirming the decision of the district court, was entered on March 26, 1974. The petition for a writ of certiorari was filed on May 13, 1974. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

QUESTION PRESENTED

Whether the statutory scheme which provides for direct review in the court of appeals of food labelling regulations issued by the Commissioner of Food and Drugs, forecloses challenges to the regulations by suit in the district courts.

STATUTORY PROVISIONS INVOLVED

Section 701(e) and (f) of the Federal Food, Drug, and Cosmetic Act of 1938, as amended, 21 U.S.C. 371(e) and (f), and the relevant portions of Section 10 of the Administrative Procedure Act, now 5 U.S.C. 702-706, are set forth at Pet. App. D.

STATEMENT

In 1962 the Commissioner of Food and Drugs proposed modification of existing regulations governing the labelling of foods for special dietary use. 27 Fed. Reg. 5815. He held public hearings and considered objections pursuant to Section 701(e) of the Federal Food, Drug, and Cosmetic Act of 1938, as amended (hereafter the Act), 21 U.S.C. 371(e). Proposed final orders signed by Charles C. Edwards, Commissioner of Food and Drugs, were published on January 19, 1973. 38 Fed. Reg. 2143-2150, 2152-2162. The orders revised existing regulations governing the labelling of foods for special dietary use and set forth definitions and standards of identity for dietary supplement of vitamins and minerals.

Before the time for filing exceptions to these proposed orders expired, Commissioner Edwards resigned. On July 12, 1973, Alexander M. Schmidt was sworn in as Commissioner. On July 25, 1973, Commissioner Schmidt signed the final orders, which were published on August 2, 1973. 38 Fed. Reg. 20708-20718, 20730-20740. Each set of regulations was preceded by a preamble which summar-

ized the objections to the changes and explained the reasons for their rejection or adoption. Commissioner Schmidt stated in the preamble that he had "considered the evidence received at the hearing, the hearing examiner's report, and all the exceptions and written arguments which were filed." 38 Fed. Reg. 20712, 20734.

Petitioners attacked the validity of these regulations in separate actions in the court of appeals and district court. On August 3, 1973, pursuant to Section 701(f)(1) of the Act, 21 U.S.C. 371(f)(1), they filed a petition for review in the Court of Appeals for the Second Circuit. While that proceeding was pending, on August 28, 1973, they filed a complaint in the district court seeking, *inter alia*, an injunction prohibiting the Food and Drug Administration from enforcing the regulations. Before the district court they contended, in essence, that because of the length of the record and other orders also considered by Commissioner Schmidt during his first thirteen days in office, Dr. Schmidt could not have exercised his independent judgment when he approved the challenged regulations. Petitioners asserted that the district court had jurisdiction under 21 U.S.C. 371 (f)(6) and Section 10 of the Administrative Procedure Act, now 5 U.S.C. 702-706.

The district court dismissed the complaint for lack of subject matter jurisdiction. The court reasoned (Pet. App. A, pp. A7-A8) that it would have jurisdiction to hear attacks on the validity of regulations promulgated pursuant to 21 U.S.C. 371(e) only if the court of appeals review provided in 21 U.S.C. 371(f)(1) were inadequate. The district court concluded (Pet. App. A, pp. A9-A10) that review by the court of appeals would be adequate. It noted that the court of appeals could if necessary arrange for the taking of evidence, and could make factual determinations.

Thereafter, petitioners filed a motion to adduce additional evidence. In the court of appeals proceeding under 21 U.S.C. 371(f)(1), they sought to depose Commissioner Schmidt or, in the alternative, the appointment of a special master to hear relevant testimony.

The court of appeals denied the motion (Pet. App. C). The court concluded (Pet. App. C, p. C5) that it had power to grant the relief requested by ordering depositions, by appointing a special master, or if necessary, by itself hearing the evidence. However, the court held (Pet. App. C, pp. C6-C10) that petitioners had failed to make the requisite showing of bad faith or improper behavior which, under this Court's decisions, would justify further inquiry. *National Nutritional Foods Ass'n* v. *Food and Drug Administration,* 491 F. 2d 1141 (C.A. 2).

The court of appeals then issued an order (Pet. App. B) summarily affirming the decision of the district court that it lacked subject matter jurisdiction.

ARGUMENT

The only matter ripe for review is the court of appeals' affirmance of the district court's ruling that it lacks subject matter jurisdiction to review the challenged regulations (Pet. 1).[1] That decision presents no conflict

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[1]Petitioners concede that the court of appeals' refusal (Pet. App. C) to allow a *de novo* factual inquiry into Commissioner Schmidt's consideration of the regulations was interlocutory (Pet. 12). The merits of the direct review proceeding were decided by the court of appeals on August 15, 1974. *National Nutritional Foods Association* v. *Food and Drug Administration,* C.A. 2, Nos. 73-2129, etc. Petitioners omitted any challenge to Commissioner Schmidt's competence from their briefs or arguments on the merits, and the court of appeals did not discuss it in its final decision, *supra.* We therefore do not discuss the questions (Nos. 1 and 2) in the petition which are addressed to the competence issue.

with any other decision and is correct, since Congress has provided an adequate remedy in the procedures for direct review in the court of appeals which petitioners pursued.

1. Neither 21 U.S.C. 371(f)(6), a saving clause which declares that remedies under the Act do not substitute for existing remedies, nor 5 U.S.C. 703, the judicial review provision of the Administrative Procedure Act, confers jurisdiction on the district court in this case. The procedure for direct review in the court of appeals set forth in 21 U.S.C. 371(f)(1) is exclusive and parties are not free to elect to sue in the district court.

The legislative history of Section 701(f) of the Act, 21 U.S.C. 371(f), shows that a petition to the court of appeals is the exclusive remedy for a party adversely affected by an order issued under 21 U.S.C. 371(e). When S. 5, the bill which became the Federal Food, Drug, and Cosmetic Act, was first passed in the House, it contained a saving clause identical to 21 U.S.C. 371(f)(6) and a separate clause placing review jurisdiction in the district courts. See 83 Cong. Rec. 7891; Dunn[2] 810-811, 930-931. This review procedure was adopted over strong objections that district court review would be used as a delaying tactic seriously impeding the effective enforcement of the Act.[3] During House debate an amendment to transfer the review function to the court of appeals was defeated (83 Cong. Rec. 7891, 7898, 7903; Dunn 931-932,

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[2]Dunn, *Federal Food, Drug, and Cosmetic Act (1938)* (hereinafter referred to as "Dunn") contains the full legislative history of the 1938 Act.

[3]The proposed review provisions met with strong opposition from a minority of the House Committee on Interstate and Foreign Commerce, the Secretary of Agriculture, the Department of Justice, and

950, 963). In the House-Senate Conference Committee, however, the bill was modified to its present form, providing for direct review in the court of appeals instead of review in the district court. H. Conf. Rep. No. 2716, 75th Cong., 3d Sess., pp. 16-18; Dunn 986-988. Petitioners' interpretation of the saving clause, 21 U.S.C. 371 (f)(6), would, therefore, restore a method of review deliberately rejected by Congress in favor of direct review in the courts of appeals. Cf. *Abbott Laboratories* v. *Gardner*, 387 U.S. 136, 145-146.

The regulations involved in *Abbott Laboratories* v. *Gardner, supra*, were not adopted pursuant to 21 U.S.C. 371(e) and therefore were not reviewable in the court of appeals under 21 U.S.C. 371 (f)(1). This Court held that in those circumstances review was available in the district court. In discussing the application of 21 U.S.C. 371 (f)(1) review to orders issued pursuant to 21 U.S.C. 371(e), however, the Court stated (387 U.S. at 146):

> [W]hen the special provisions apply, presumably they must be used and a court would not grant injunc-

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various consumer organizations. The minority feared serious delays which "would postpone indefinitely the consumer protection." H. Rep. No. 2139, 75th Cong., 3d Sess., Part 2, pp. 1-3; Dunn 834-836. The Secretary of Agriculture concluded that the proposed district court review would so "hamstring" the Act's enforcement "as to amount to a practical nullification of the substantial provisions of the bill." H. Rep. No. 2139, 75th Cong., 3d Sess., Part 2, pp. 3-4; Dunn 836. Similar fears were expressed by a wide variety of consumer organizations and members of Congress. See, *e.g.*, 83 Cong. Rec. 7772-7773, 7775-7777, 7779, 7785-7786, 7787-7788; Dunn 839-840, 842-845, 858-863, 876-880, 883-884.

tive or declaratory judgment relief unless the appropriate administrative procedure is exhausted.[4]

Thus, under the reasoning of *Abbott*, if review in the court of appeals under 21 U.S.C. 371 (f)(1) is available, that procedure must be pursued, and jurisdiction does not exist in the district court.[5] Cf. *Whitney Bank* v. *New Orleans Bank*, 379 U.S. 411, 414, 420; *PBW Stock Exchange, Inc.* v. *Securities and Exchange Commission*, 485 F. 2d 718 (C.A. 3), certiorari denied, No. 73-1134, April 29, 1974.

2. There is no substance in petitioners' contention that review by the court of appeals is "inadequate" and that the district court therefore has jurisdiction under 5 U.S.C. 703. Petitioners claim (Pet. 11) that resolution of the issues involved may require the taking of additional evidence not in the record. They do not deny that the court of appeals has the power in cases arising under 21 U.S.C. 371(f) to obtain such evidence (see Pet. App. C, p. C5), but argue that, nevertheless, such direct review "is neither available nor adequate

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[4] See Notes of the Advisory Committee on Federal Rule of Civil Procedure 57, reprinted in 28 U.S.C. App., at 7823: "A declaration may not be rendered if a special statutory proceeding has been provided for the adjudication of some special type of case * * *." See also 6A Moore, *Federal Practice* §57.08[3] (2d ed. 1971).

[5] This result is consistent with the general principle for judicial review of agency decisions set forth in Section 10 of the Administrative Procedure Act, 5 U.S.C. 703, that "The form of proceeding for judicial review is the special statutory review proceeding * * * specified by statute * * *." It is also consistent with *Nader* v. *Volpe*, 466 F. 2d 261, 271-272 (C.A.D.C.), involving interpretation of a saving clause, in an unrelated Act, which is identical to the saving clause in 21 U.S.C. 371(f)(6).

within the meaning of 5 U.S.C. 703 * * * when it is dependent on the exercise of extraordinary 'inherent' fact-finding authority by a court of appeals" (Pet. 11).

Apparently petitioners are contending that because the court of appeals has discretion to decide when extra-record fact finding is necessary, the possibility that it may decide, as it did in this case (Pet. App. C, p. C10), that it is unnecessary renders the remedy inadequate. But the court of appeals had made plain that it will use its authority to obtain additional evidence in an appropriate case, and it properly held that such a case was not presented here. Nothing in the review provisions of the Administrative Procedure Act or in any decision of this Court requires more. Extra-record review is obviously the rare exception, not the rule. Cf. *United States* v. *Morgan*, 313 U.S. 409, 422; *De Cambra* v. *Rogers*, 189 U.S. 119, 122; 2 Davis, *Administrative Law Treatise* 59 (1958).

CONCLUSION

For the reasons stated the petition for a writ of certiorari should be denied.

Respectfully submitted.

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SEPTEMBER 1974.